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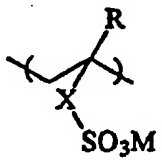
(54) Title: METHOD FOR CLEANING CONTACT LENSES UTILIZING POLYSULFONATES

(57) Abstract

Contact lenses are cleaned by contacting the lenses with a cleaning composition containing an effective amount of one or more sulfonate polymers comprising monomeric units represented by formula (I), wherein X represents a bond or a linking; M represents a salt-forming cation; and R is a hydrogen or alkyl group. The cleaning compositions can also be employed at elevated temperatures or may contain suitable antimicrobial agents in order to simultaneously clean and disinfect the lenses.



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METHOD FOR CLEANING CONTACT LENSES UTILIZING POLYSULFONATES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to a method for cleaning contact lenses utilizing a cleaning composition including one or more polysulfonates. In one embodiment of the invention, lenses are immersed within the subject cleaning composition. Other embodiments of the invention include heating and/or agitating the cleaning composition while a lens remains immersed therein. Still other embodiments of the invention are described.

2. Description of Art

Contact lenses require periodic cleaning to remove various debris which build-up upon the lens during the normal course of wear. Such debris include proteinaceous, oily, sebaceous, and related organic matter. If such debris are not properly removed, both the wettability and optical clarity of the lenses are substantially reduced resulting in discomfort for the wearer. Of the noted debris, proteinaceous deposits such as lysozyme, are difficult to remove from lenses, particularly soft contact lenses of the high water, ionic type, (F.D.A. Group IV lenses). This is believed to be due to ionic interactions formed between proteinaceous materials and the surface of the lens. More specifically, it is believed that the positively charged functional groups of protein molecules form ionic bonds with the negatively charged functional groups of the lens material.

As a result of the difficulty in removing proteinaceous deposits from lenses, cleaning regimens typically require the use of proteolytic enzymes and the step of "rubbing" the lenses. Lens cleaning regimens which do not utilize proteolytic enzymes are known, however. An example of such a regimen is provided in U.S. Patent No. 5,370,744 to Chowhan et al.. issued December 6, 1994, which discloses a method for cleaning and disinfecting a contact lens with a single aqueous solution containing a

disinfectant agent and a cleaning agent (e.g. polysulfonate such as polystyrene sulfonate having a molecular weight of approximately 90 to 600). The method comprises the critical steps of: rubbing a small amount of the solution on both surfaces of the lens, rinsing the lens with the solution, and then soaking the lens in the solution for a time sufficient to achieve disinfection.

Another example of cleaning methodology requiring rubbing is provided in U.S. Patent No. 3,907,985 to Rankin issued September 23, 1975. This reference discloses an ophthalmic solution comprising an aqueous solution of polystyrene sulfonate having a molecular weight between 75,000 to 10,000,000, and preferably polyethylene glycol. The solution is disclosed as providing a lubricant and cushioning effect to traumatized eyes along with providing a cleaning function. The cleaning method disclosed comprises the steps of soaking a lens in the noted ophthalmic solution followed by rubbing the lens between the fingers and subsequently rinsing the lens with water. Although the reference stated that the disclosed regimen cleaned debris from lenses, there was no specific description of protein removal.

As contact lens wearers commonly fail to comply with cleaning regimens which require the step of "rubbing," or the use of multiple solutions or tablets, efforts have been made to design cleaning methods as convenient and straight forward as possible. To this end, a number of "no rub" approaches have been developed. For example, U.S. Patent No. 3,954,965 to Boghosian et al. issued May 4, 1976 discloses a method for sterilizing and preventing the formation of proteinaceous deposits on contact lenses. The method comprises soaking the lens in a solution including a sterilization material and a protein reacting compound (e.g. pectin, heparin, chondroiton sulfate, etc.), for at least 30 minutes at a temperature of between 40° to 100°C.

Another example of a "no rub" cleaning regimen is disclosed in U.S. Patent No. 4,500,441 to Tanaka et al. issued February 19, 1985. This reference discloses a cleaning and storage aqueous solution comprising a monomeric anionic surface active agent (e.g. sodium alkylbenzene sulfonates), and a non-ionic surface active agent. The cleaning method comprises soaking the lenses in the cleaning composition for an

acceptable time period. The reference goes on to provide that a more remarkable cleaning effect is obtained by rubbing the lens with the cleaning composition.

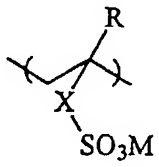
U.S. Patent No. 4,259,202 to Tanaka et al. issued March 31, 1981 also discloses a "no rub" lens cleaning method which consist of soaking a lens in a solution including a specific monoester of a saccharose with a fatty acid, and preferably a polysaccharide (alkali metal salts of chondroiton sulfuric acid, pectic acid, dextran, xanthan gum, etc.). Lenses may be sterilized by subsequently heating.

U.S. Patent No. 4,738,790 to Miyajima et al. issued April 19, 1988 discloses a method for removing proteinaceous depositions from contact lenses by soaking the lenses in a detergent composition comprising an anionic surfactant such as alkylbenzene sulfonate, alkyl sulfonate, olefin sulfonate, etc., and at least one compound selected form the thiourea and reductants. The reference states that soaking in a heated solution improves detergency.

Although progress has been made in developing simplified lens cleaning regimens, new methodologies are sought which effectively remove deposited proteinaceous material with out requiring such steps as rubbing or the use of multiple solutions, tablets, etc.

SUMMARY OF THE INVENTION

According to the present invention, a method for cleaning contact lenses is provided comprising contacting the lenses with a composition containing a sulfonate polymer comprising monomeric units represented by the formula:



wherein X represents: a bond or a linking group; M represents a salt-forming cation; and R is a hydrogen or alkyl group.

Also provided is a method for simultaneously cleaning and disinfecting contact lenses wherein contact lenses are contacted with the above-noted cleaning composition for a time period and temperature sufficient to disinfect and clean the lenses.

Yet another method is provided for simultaneously cleaning and disinfecting contact lenses comprising contacting the lenses with the subject cleaning composition further including a sufficient amount of an antimicrobial agent, for a time sufficient to clean and disinfect the lenses.

Still other methods are provided wherein contact lenses are subjected to agitation with fluids, including the subject cleaning composition.

The present method is particularly useful in effectively removing proteinaceous deposits from contact lenses without requiring the additional step of rubbing and/or the use of multiple solutions or tablets.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be used with all contact lenses such as conventional hard, soft, rigid gas permeable, and silicone lenses, but is preferably employed with soft lenses such as those commonly referred to as hydrogel lenses prepared from monomers such as: hydroxyethylmethacrylate, vinylpyrrolidone, glycerol-methacrylate, methacrylic acid or acid esters and the like. Hydrogel lenses typically absorb significant amounts of water, e.g. from about 4 to 80% by weight.

The present method consists essentially of contacting a contact lens with a cleaning composition, the nature of which is described in detail below with reference to Formula I. The present method has been specifically designed to avoid the step of rubbing the lens, or the use of other similar steps wherein one is required to make mechanical contact (e.g. scrubbing, brushing, etc.) with the lens. The step of "contacting" the lens with the cleaning composition is typically performed by immersing the lens within the cleaning composition. Permitting the lens to soak within the cleaning composition is also contemplated by the term "contacting." The length of time of such contact between the lens and the cleaning composition may vary depending upon a number of factors including; the amount and type of debris on the lens, the type of lens, the composition of the cleaning composition including the concentration of the sulfonate material therein, and the precise cleaning regimen utilized. However, typical cleaning regimens often include soaking lenses within the subject cleaning composition for times between fifteen minutes to twelve hours.

In some embodiments of the present method, the step of agitation is included. The term "agitation" as used in connection with the present method is intended to define a fluid interaction with and/or about the contact lens. More specifically, the term is intended to include shaking, stirring, swirling (e.g. as achieved by convention current resulting from heating of fluid), rinsing and similar procedures wherein fluid is moved about the contact lens. Although the fluid utilized in such agitation may comprise solutions, dispersions, colloids, latexes and suspensions, it is intended that term "agitation" be distinguished from large scale mechanical-type interactions with the lens, e.g. rubbing, scrubbing, brushing, or the like. It is generally preferred that the fluid utilized in such agitation consist of the subject cleaning composition, although other fluid may be used, e.g. saline, water, and the like.

In some embodiments of the present method, lenses may be simultaneously disinfected while being cleaned by the inclusion of an antimicrobial agent within the cleaning composition. Alternatively, lenses may be cleaned and disinfected in separate steps by soaking lenses in the subject cleaning composition and a separate disinfecting solution. As an alternative to using an antimicrobial agent in combination with the cleaning composition, the cleaning composition may be heated while the lenses remain in contact therewith, e.g. while the lenses soak within the cleaning composition. Techniques and devices for performing such heating are well known in the art and are commercially available. These devices typically raise the temperature of the composition inside their wells to between about 60°C to 100°C for about 20 to 60 minutes, as required to disinfect the lenses. As with the use of antimicrobial agents, heating techniques offer added convenience as cleaning and disinfection take place simultaneously. Furthermore, the step of heating provides agitation of the cleaning composition (by way of convection currents) about the lens which provides improved cleaning.

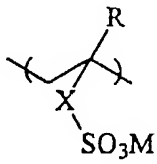
In some embodiments of the present invention, a lens is subjected to an agitation process wherein the lens may be rinsed with the subject cleaning composition, or other fluid such as saline, multi-purpose solution, water, or the like. Alternatively, or in addition to such rinsing, the lens may be immersed in the subject cleaning composition, or other fluids such as saline, multi-purpose solution, water, etc., and agitated (e.g. by

shaking the container holding the cleaning composition and lens for a few seconds). Following such agitation, the lens is permitted to soak within the subject cleaning solution for a sufficient length of time to effectively clean the lens, typically between fifteen minutes to twelve hours. As previously stated, the cleaning solution may include one or more antimicrobial agents such that disinfection occurs simultaneously with cleaning. After soaking, the lens may be subjected to agitation, in its various forms, as previously described. Alternatively, a lens may be contacted with the subject cleaning composition for a sufficient time to clean the lens, e.g. remove protein, followed by rinsing

In other embodiments of the invention, the cleaning composition is heated while the lens soaks therein. (In some embodiments, lenses may be "pre-soaked" in the subject cleaning composition prior to such heating). As with embodiments previously described, the lens may be subjected to agitation (in its various forms) before or after soaking within the heated cleaning composition. Thus, in its various embodiments, the present method obviates the need for rubbing or other similar mechanical-type interactions with the lens.

The cleaning composition utilized in the present method includes one or more sulfonate polymers comprising monomeric units represented by Formula I, provided in a suitable carrier.

Formula I:



wherein X represents: a bond or a linking group; M represents a salt-forming cation, and R represents a hydrogen or alkyl. Examples of salt-forming cations include but are not limited to: hydrogen, metals (sodium, calcium, potassium, etc.), ammonium, and amino. When R is an alkyl, lower alkyl groups are preferred, e.g. methyl, ethyl, etc.

As stated, X represents either a bond or linking group. When X is a bond, the bond in question is formed between a carbon atom of the polymeric chain and the sulfur atom of the pendant sulfonate group, e.g. as in poly(vinylsulfonate). The term "linking group" is intended to cover chemical groups which serve to link or connect the

hydrocarbon backbone of the polymer with the sulfonate group but which do not substantially detract with the cleaning effect of the sulfonate material. Suitable linking groups are well known in the art and include by way of example: alkyl groups (e.g. methyl, ethyl, isopropyl, dodecyl, etc.); cyclic groups including alicyclic (e.g. cyclohexane), heterocyclic (e.g. 1,4-dioxane, morpholine, pyrrolidine, etc.), aromatic (e.g. benzene, naphthalene, pyridine, etc.) aralkyl groups, alkaryl groups, and the like. Examples of some preferred linking groups include: a phenyl group, a substituted phenyl group (as in poly(anetholesulfonate)), and lower alkyl groups (e.g. methyl, ethyl). Such linking groups may be substituted or unsubstituted. Examples of typical substituents for such groups include: methoxy (e.g. polyanetholesulfonate), ethylcarboxyl (e.g. polysulfoethyl methacrylate), propylcarboxyl (e.g. poly3-sulfopropyl methacrylate), and alkylamido (e.g. poly(sulfoethyl acrylamide)).

The sulfonate polymers of the present invention include copolymers comprising at least one, but alternatively several of the monomeric units described with respect to Formula I. That is, a sulfonate polymer of the present invention may comprise a copolymer including different monomeric units as represented by Formula I, wherein the groups represented by X, R, and M vary between monomeric units. Furthermore, other non-sulfonate containing monomeric units may also be included within the subject sulfonate polymer. Examples of such monomeric units include styrene, methylstyrene, ar-methylstyrenes, vinylnaphthalenes, ar-chlorosytrenes, isobutylene, ethylenically unsaturated esters, e.g. 1 to 12 carbon atom alkyl esters of acrylic or methacrylic acids, vinyl esters of fatty acids such as vinyl acetate, vinyl chloride, vinylidene chloride, methyl isopropenyl ketone, methyl vinyl ether, and acrylonitrile. Such materials and their corresponding synthesis are well known in the art. When such non-sulfonate monomeric units are copolymerized with the sulfonate monomeric units described with reference to Formula I, the resulting copolymer preferably comprises at least fifty percent by weight of the subject sulfonate monomeric units.

As stated, the present cleaning composition includes at least, but possibly several different sulfonate polymers as described herein. The sulfonate polymers are preferably water soluble and have a molecular weight greater than about 2000. More

preferably, the sulfonate polymers have a molecular weight of between about 18,000 to 200,000.

A particularly preferred class of sulfonate polymers useful in the present invention are polystyrene sulfonates. The term polystyrene sulfonates is intended to include the class of polymers which are characterized by the polymerization of alkenyl aromatic sulfonates or the sulfonation of polymers of alkenyl aromatics. This class of polymers is intended to include both homopolymers and copolymers of styrene sulfonate along with homo- and copolymers of styrene sulfonate analogs. Such polystyrene sulfonates along with their corresponding synthesis are well known in the art. Examples of preferred polystyrene sulfonates for use in the present invention include poly(sodium 4-styrenesulfonate) and sodium poly(anetholsulfonate). Examples of commercially available polystyrene sulfonates useful in the present invention include those sold under the mark VERSA-TL (e.g. VERSA-TL 70, VERSA-TL 130, VERSA-TL 502) and Flexan 130, all available from the National Starch and Chemical Company of Bridgewater, New Jersey. (Cosmetic and pharmaceutical grades of such materials are preferred over industrial grades). Of the polystyrene sulfonates described, those which are water soluble are preferred. Furthermore, polystyrene sulfonates having molecular weights greater than 2000 are preferred. Polystyrene sulfonates having molecular weights from 18,000 to 200,000 are particularly preferred.

In addition to the sulfonate polymers described above, the subject cleaning composition may include other constituents including suitable carriers which do not adversely affect, to any significant extent, the activity of the sulfonate materials previously discussed. By way of example only, the solution may include one or more of: antimicrobial agents, buffering agents, tonicity adjusting agents, cleaners, surfactants, and the like. Furthermore, the solution may comprise a saline or multi-purpose solution such as Sensitive Eyes ®Plus from Bausch & Lomb or ReNu® from Bausch & Lomb. Although surfactants may be used within the subject cleaning composition, their use is neither required nor preferred. That is, the subject cleaning composition effectively cleans contact lenses without the use of surfactants.

Examples of antimicrobial agents which may be used within the subject cleaning composition include but are not limited to: polyhexamethylene biguanide, polyquaternium-1, BAK, sorbic acid and its salts, thimerosol, hydrogen peroxide, iodine and iodophors, and the like. Some cleaning compositions within the scope of the subject invention may reduce the effectiveness of some antimicrobial agents, e.g. biguanides, quaternary ammonium compounds such as polyquaternium-1 and BAK. As such, preliminary screening experiments may be necessary in order evaluate the effectiveness of specific antimicrobial agents when utilized as part of specific cleaning compositions.

The cleaning compositions of the present invention preferably have a pH between about 6 to 10, preferably 6 to 9, but more preferably between about 7 to about 8. The osomolality of the subject cleaning compositions is preferably below about 600, and more preferably between about 145 to about 320.

The cleaning composition of the present invention employs an effective amount of one or more of the sulfonate polymers (as described with reference to Formula I) to clean contact lenses. An effective amount is that required to remove a substantial portion of the proteinaceous deposits, which occur during normal wear of contact lenses, in a reasonable time period. The precise amount of sulfonate polymer required to make an effective cleaner will depend on several factors including the specific type(s) of sulfonate polymer(s) used, the amount of proteinaceous material deposited on the lenses, the desired soaking period, the specific type of materials comprising the lenses, and the like. It will be appreciated by those skilled in the art that the sulfonate polymer concentrations useful herein will be adjusted depending upon the time allowed for removing the proteinaceous matter, the other components in the cleaning composition and the factors previously mentioned. However, the sulfonate polymers will generally be present in the subject cleaning solution in an amount from between about 0.001% to about 10%, with from about 0.01% to 1% weight by volume being preferred, and 0.1% being most preferred.

EXAMPLES

As a further illustration of the present invention, several examples were prepared and are provided below. The lenses used in the following examples were etafilcon A lenses, (FDA designation Group IV; high water, ionic). Each lens was subjected to a protein deposition procedure followed by soaking in 10 ml of a cleaning composition for four hours, after which, cleaning efficacy was evaluated utilizing a modified Ninhydrin procedure for total lens protein.

PROTEIN DEPOSITION

The lenses of following examples were each subjected to a protein deposition procedure (pre-treatment) designed to provide proteinaceous deposits on the lenses. The procedure consisting of placing each lens into a clean glass vial and subsequently adding 5 ml of a protein solution such that the lens was completely submerged therein. The vial was then sealed and placed in an approximately 37°C bath for about one hour, followed by removing the lens from the vial and rinsing it with a borate buffer saline.

The protein solution utilized in the protein deposition procedure had the following formulation:

	Percent (w/v)
Sodium Chloride	0.70
Potassium Chloride	0.17
Calcium Chloride (dihydrate)	0.0005
Sodium Bicarbonate	0.22
Lysozyme (hen, 3x crystallized)	0.10

This solution was prepared by adding the sodium chloride, potassium chloride, calcium chloride and sodium bicarbonate to about 90% of the total volume of distilled water followed by thoroughly mixing. Lysozyme was added to the solution and the resulting solution was stirred for approximately 30 minutes. The solution was brought up to 100% volume with distilled water and the pH was readjusted with 1N HCl or 1N NaOH to about 7.2. The acceptable range for osmolality of the solution was between about 280 to 320 mOsm/Kg.

The borate buffered saline utilized in the pre-treatment procedure and in the examples described below had the following formulation:

	Percent (w/v)
Boric Acid	0.85
Sodium Borate	0.09
Sodium Chloride, USP	0.45

The borate buffered saline solution was prepared by adding the sodium borate, boric acid, and sodium chloride to about 80% to 95% of the total volume. The pH of this solution was adjusted to about 7.2 (utilizing 1N HCl or 1N NaOH as necessary). The solution was subsequently brought up to 100% volume and the pH was readjusted to about 7.2. The acceptable range for osmolality for the borate buffered saline solution was between about 280 to 320 mOsm/Kg.

CLEANING EVALUATION

A modified Ninhydrin procedure (for more information regarding Ninhydrin procedures, see Shibata and Matoba, *Modified Colorimetric Ninhydrin Methods for Peptidase Assay*, Analytical Biochemistry 1981; 118:173-184,) was used to determine the amount of proteinaceous material removed from the lenses by way of various cleaning methods described below. The procedure was substantially as follows: After being cleaned by way of the various cleaning methods described below, each lens was subsequently cut into quarters and the four quarters where placed into a glass test tube. The protein bound to each lens was hydrolyzed by adding 1 ml of 2.5N sodium hydroxide to each tube such that the individual lens pieces therein were completely covered with the base solution. The tubes were capped, placed into a preheated heating block (about 100°C) for approximately two hours, and then removed from the block. The tubes were allowed to cool to room temperature (minimum 30 minutes, not to exceed 4 hours with lens pieces still in solution) and a 15 µL aliquot of contact lens hydrolysate (hydrolyzed protein from the lens) was removed from each tube, diluted in a 1 to 10 ratio (by volume) with 2.5N sodium hydroxide and subsequently placed into individual disposable polystyrene culture tubes. These culture tubes where subsequently sealed and the contents mixed. 50 µL of glacial acetic acid was added to each tube to neutralize the

sodium hydroxide. Subsequently, 400 µL of a ninhydrin reagent (described below) was added to each tube and mixed thoroughly. The tubes were then capped and heated in a water bath (or heating block) at about 90°C for approximately 20 minutes. The tubes were immediately transferred to an ice bath to cool for approximately 5 minutes. Upon cooling, 1.0 ml of an equal volume solution of isopropyl alcohol and distilled water was added to each tube. The mixture within the tubes was then thoroughly mixed and the absorbance of each tube was measured at 570 nm on a ultraviolet Spectrophotometer.

The amount of protein in each sample was calculated by comparing the absorbance of each sample to that of a known phenylalanine standard curve. The phenylalanine standard curve was prepared by using a working standard of 0.1 mg/ml phenylalanine solution in a disposable polystyrene culture tube. Appropriate dilutions were made to give a range of concentration from about 0 µg to 15 µg The phenylalanine solution was prepared by dissolving 0.1% (1mg/ml) phenylalanine into 2.5N sodium hydroxide and stirring for approximately 10 minutes.

The ninhydrin reagent used in the procedure was prepared by dissolving 1.0% ninhydrin and 0.1% stannous chloride into an appropriate amount of methyl cellosolve (ethylene glycol, monomethyl ether) that will yield 50% of the total volume. This mixture was stirred until the solids dissolved into solution. A citrate acetate buffer was then added to bring the solution up to 100%. The citrate acetate buffer was prepared by dissolving about 28.6 ml of acetic acid and 21.0 g of citric acid in approximately 850 ml of distilled water. The solution was then mixed and the pH was adjusted to about 5.0 with an appropriate base (e.g. 10N sodium hydroxide). The volume of the solution was then brought up to approximately 1 L with distilled water.

The cleaning results reported below are indicated as a percentage improvement in protein removal as compared with a substantially identical cleaning treatment utilizing only the borate buffered saline.

EXAMPLE 1

The cleaning efficacy of cleaning methods using solutions including polystyrene sulfonates with various molecular weights was evaluated. The cleaning composition utilized in this example consisted of a solution having the following formulation:

	Percent (w/v)
Boric Acid	0.60
Sodium Borate	0.29
Sodium Chloride, USP	0.42
Disodium EDTA	0.025
Sorbic Acid	0.11
Polystyrene sulfonate	0.10

This solution was prepared by adding the sodium borate, sorbic acid, disodium EDTA, boric acid, and sodium chloride to about 80% to 95% of the total volume. An aqueous solution of polystyrene sulfonate is added to the solution and the volume is brought up to 100% with distilled water. The resulting solution is mixed for not less than 15 minutes at which time the pH is adjusted to about 7.2 to 7.6 with 1N sodium hydroxide or 1N hydrochloric acid, if necessary.

Cleaning was performed by soaking a pre-treated lens (i.e. lens having protein deposited thereon as previously described) in 10 ml of each of the test cleaning composition at room temperature for about 4 hours. The cleaning compositions utilized in each sample where substantially identical but for the specific type of sulfonate material utilized. More specifically, the following sulfonate materials were used: Example 1-A, Monomeric styrene sulfonate having a Mw of approximately 206 available from Polysciences Co.; Example 1-B, 4-sulfonic calix(4)arene having a Mw of approximately 853 available form Janssen Co.; Examples 1-C through 1-F, Poly(sodium 4-styrenesulfonate) having a Mw of approximately 1800; 15,000; 18,000; and 20,000, respectively, all available from Polysciences Co.; and Examples 1-G through 1-J, Poly(sodium 4-styrenesulfonate) having a Mw of approximately 35,000; 70,000; 200,000; and 500,000; respectively, all available from National Starch and Chemical Co. under the VERSA-TL mark.

The lenses were then rinsed with borate buffered saline to prevent solution carry-over and evaluated for protein removal according to the procedure previously described. The results are provided below in Table 1.

TABLE 1

Example No.	Sulfonate Polymer Utilized in Cleaning composition (Mw)	% Increase in Protein Removal as Compared with Borate Buffered Saline
1-A	Monomeric styrene sulfonate (206)	4
1-B	4-Sulfonic calix(4)arene (853)	0
1-C	poly(sodium 4-styrenesulfonate) (1800)	6
1-D	poly(sodium 4-styrenesulfonate) (15,000)	19
1-E	poly(sodium 4-styrenesulfonate) (18,000)	29
1-F	poly(sodium 4-styrenesulfonate) (20,000)	33
1-G	poly(sodium 4-styrenesulfonate) (35,000)	31
1-H	poly(sodium 4-styrenesulfonate) (70,000)	33
1-I	poly(sodium 4-styrenesulfonate) (200,000)	29
1-J	poly(sodium 4-styrenesulfonate) (500,000)	27

As is demonstrated by the data of Table 1, optimum cleaning was obtained when using a cleaning composition including polystyrene sulfonate having a molecular weight between 18,000 to 200,000 (i.e. Example Nos. 1-E through 1-I); whereas, little cleaning was achieved when using cleaning compositions including sulfonate materials having molecular weights under 1,800 (i.e. Example Nos. 1-A through 1-C).

EXAMPLE 2

The cleaning efficacy of cleaning methods using cleaning compositions having various concentrations of poly(sodium 4-styrenesulfonate) (Mw of approximately 150,000 available from the National Starch and Chemical Co. under the mark Flexan 130) was evaluated. Cleaning was evaluated by soaking pre-treated (i.e. lenses having protein deposited thereon as previously described) lenses in 10 ml of the test cleaning composition at room temperature for about 4 hours. The test cleaning compositions utilized in each sample where substantially identical but for the concentration of poly(sodium 4-styrenesulfonate) utilized therein, as indicated in Table 2 below. Unlike

Example 1, however, the cleaning composition utilized included the borate buffered saline solution as previously described. The lenses were subsequently rinsed with fresh borate buffered saline to prevent solution carry-over and evaluated for protein removal according to the procedure previously described. The results are provided below in Table 2.

TABLE 2

Example No.	Concentration of Poly(sodium 4-styrene sulfonate), Indicated as Percent (w/v)	% Increase in Protein Removal as Compared with Borate Buffered Saline
2-A	1%	29.5
2-B	0.5%	32.2
2-C	0.1%	42.1
2-D	0.05%	45.9
2-E	0.01%	45.5

As indicated by the data provided in Table 2, all the test cleaning compositions provided excellent cleaning.

EXAMPLE 3

The cleaning efficacy of cleaning compositions including 0.5 % poly(sodium 4-styrenesulfonate), (Mw of approximately 150,000 available from the National Starch and Chemical Co. under the mark Flexan 130), at various pH levels was evaluated. Cleaning was evaluated as in Examples 1 and 2, that is, by soaking a pre-treated lens (i.e. lens having protein deposited thereon as previously described) in 10 ml of the test cleaning composition at room temperature for about 4 hours. The test cleaning compositions utilized in each sample where substantially identical to one another but for the pH of the solution, as indicated in Table 3 below. As in Example 2, the cleaning composition included the borate buffered saline having the composition as previously described. After soaking, the lenses were subsequently rinsed with fresh borate buffered saline to prevent solution carry-over and evaluated for protein removal according to the procedure previously described. The results are provided below in Table 3.

TABLE 3

Example No.	pH of Cleaning composition	% Increase in Protein Removal as Compared with Borate Buffered Saline
3-A	2	0.8
3-B	4	6.8
3-C	6	24.8
3-D	7	43.0
3-E	8	43.5
3-F	9	38.0

As indicated by the data presented in Table 3, cleaning compositions having a pH above 4 demonstrate more effective cleaning, with pH values of about 7 to 8 being particularly preferred, (i.e. Example Nos. 3-D and 3-E). This result was somewhat unexpected. pKa values associated with most contact lens materials containing carboxylate groups is typically around 3.5 to 5.0; whereas, the sulfonate groups of the polymer within the cleaning composition typically have pKa values of around -7. Thus, at low pH levels, one would anticipate the negative charge of the lens material to be neutralized by the high concentration of hydrogen ions, while the sulfonate groups of the cleaning composition would likely maintain their negative charge. If such were the case, lower pH levels would promote the interaction between the sulfonate polymer and the protein materials over the ionic interaction between the protein materials and the lens. However, as illustrated by the data in Table 3, this was not the case. Thus, an unexpected advantage of the invention is that maximum cleaning is achieved at bio-compatable pH levels, i.e. around a pH of 7.

EXAMPLE 4

The effect of solution osmolality upon cleaning efficacy was evaluated by utilizing cleaning compositions having similar composition as utilized in Examples 2 and 3. Cleaning was evaluated as in Examples 1-3. The test cleaning compositions utilized in each sample of this example where substantially identical but for percentage of sodium chloride used therein to alter the osmolality. The specific osmolality values for each test composition are indicated in Table 4 below. The lenses were rinsed with a borate

buffered saline after cleaning to prevent solution carry-over and evaluated for protein removal according to the procedure previously described. The results are provided below in Table 4.

TABLE 4

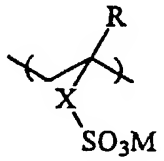
Example No.	Osmolality	% Increase in Protein Removal as Compared with Borate Buffered Saline
4-A	145	54
4-B	305	44
4-C	465	38
4-D	600	29

As indicated by the data presented in Table 4, all of the test cleaning compositions provided excellent cleaning; however, more effective cleaning was achieved for cleaning compositions having osmolality values of between about 145 to 305.

Based upon the foregoing, it should be apparent to those skilled in the art that the present invention is not limited by the examples set forth above and that the use of specific compositions can be determined from the specification without departing from the invention as herein disclosed and described. It should be understood that the scope of the present invention includes all modifications and variation that fall within the scope of the attached claims.

CLAIMS

1. A method for cleaning a contact lens consisting essentially of contacting a lens with a cleaning composition including one or more sulfonate polymers comprising monomeric units represented by the formula:



wherein X represents: a bond or a linking group; M represents a salt-forming cation; and R is a hydrogen or alkyl group.

2. A method as set forth in claim 1 further including the step of agitating the cleaning composition about the lens.

3. A method as set forth in claim 2 wherein the step of agitation includes at least one of shaking and rinsing.

4. A method as set forth in claim 1 further including the step of heating the cleaning composition while the lens remains in contact therein.

5. A method as set forth in claim 4 further including the step of agitating the cleaning composition about the lens.

6. A method as set forth in claim 1 wherein M, the same or different as among monomeric units, is selected from the group consisting of: hydrogen, sodium, calcium, potassium, ammonium, and amino.

7. A method as set forth in claim 1 wherein R is hydrogen or a methyl group.

8. A method as set forth in claim 1 wherein the sulfonate polymer comprises polystyrene sulfonate.

9. A method as set forth in claim 1 wherein the sulfonate polymer comprises poly(sodium 4-styrenesulfonate).

10. A method as set forth in claim 1 wherein the sulfonate polymer comprises sodium poly(anetholsulfonate).

11. A method as set forth in claim 1 wherein the sulfonate polymer comprises sodium poly(vinylsulfonate).

12. A method as set forth in claim 1 wherein the sulfonate polymer has a molecular weight greater than 2000.

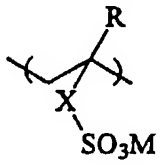
13. A method as set forth in claim 1 wherein the sulfonate polymer has a molecular weight between about 18,000 to 200,000.

14. A method as set forth in claim 1 wherein the concentration of the sulfonate polymer is between about 0.01% to 1% weight by volume.

15. A method as set forth in claim 1 wherein the cleaning composition has a pH between about 6 to 9.

16. A method as set forth in claim 1 wherein the cleaning composition has a osmolality of between about 145 to 600.

17. A method for cleaning and disinfecting a contact lens consisting essentially of contacting a lens with a cleaning composition including one or more sulfonate polymers comprising monomeric units represented by the formula:



wherein X represents: a bond or a linking group; M represents a salt-forming cation; and R is a hydrogen or alkyl group; and heating the cleaning composition under conditions to substantially disinfect the lens while the lens remains in contact therewith.

18. A method as set forth in claim 17 wherein the lens is rinsed with cleaning composition following said heating.

19. A method as set forth in claim 17 wherein prior to said step of heating, the cleaning composition is shaken while the lens is in contact therewith.

INTERNATIONAL SEARCH REPORT

In: ional Application No
PCT/US 96/08055

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C11D3/37 A61L2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C11D A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 370 744 (CHOWHAN MASOOD ET AL.) 6 December 1994 cited in the application see claims 1-4,7-10	1,8
X	EP,A,0 079 030 (SYNTEX INC.) 18 May 1983 see page 12, line 4 - page 13, line 16 see claims 1-9	1,8,11, 17
X	US,A,3 907 985 (RANKIN BILLY F.) 23 September 1975 cited in the application see example 1	1,8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
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Int ional Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US,A,3 954 965 (BOGHOSIAN M. P. ET AL.) 4 May 1976 cited in the application see claims	1,17
A	US,A,4 500 441 (TANAKA KYOICHI ET AL.) 19 February 1985 cited in the application see column 4, line 9 - line 33 see claim 1	1,15,17
A	US,A,4 259 202 (TANAKA KYOICHI ET AL.) 31 March 1981 cited in the application see the whole document	1-5,15, 17

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